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(71) Applicant (for all designated States except US): THE UNI-VERSITY COURT OF THE UNIVERSITY OF DUNDEE [GB/GB]; Dundee DD1 4HN (GB).

(72) Inventors; and

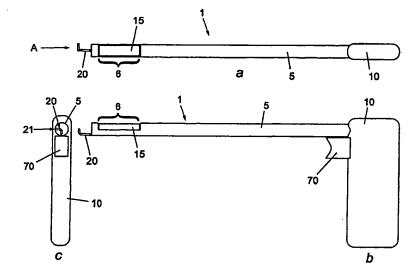
(75) Inventors/Applicants (for US only): CUSCHIERI, Alfred [GB/GB]; Denbrae Mill, Strathkiness Low Road, St. Andrews, Fife K19 9TY (GB). FRANK, Graham, Timothy [GB/GB]; 37 Naughton Road, Wormit, Newport-on-Tay, Fife DD6 8NG (GB).

(74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G5 8QA (GB). (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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(54) Title: DEVICE FOR ENDOSCOPIC DELIVERY OF SURGICAL MATERIAL



(57) Abstract

A device for the delivery of a shape memory securing member into a confined space, the device having an exit for the securing member and means to move the securing member through the exit, the device further including a magazine having a plurality of channels each of which can store a securing member is described. Preferably, each securing member is restrained in the device in a first configuration, and upon passing through the exit adopts a second configuration. One form of the magazine is a barrel. The barrel may be rotatable around an axis, and the channels can be disposed parallel to said axis or may lie in a helical configuration. This arrangement can be likened to a "revolver barrel" on a firearm. One advantage of the present invention in surgery is that it can store several sutures or ligatures to allow multiple placements without the need to withdraw the instrument from the patient.

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DEVICE FOR ENDOSCOPIC DELIVERY OF SURGICAL MATERIAL 1 2 This invention relates to a delivery device. 3 5 Minimal access surgery (MAS) allows certain operations to be carried out through small access holes thus 6 avoiding the creation of large traumatic wounds. 7 However difficulties arise in suturing surgical incisions and ligating inside the patient using current 10 instruments due to the small size of the access hole which restricts movement of the instrument. 11 12 knots in suture and ligating threads is particularly 13 difficult and time consuming. 14 15 In an attempt to overcome this problem, devices have 16 evolved for manipulating needles within the body. One 17 such device (disclosed in WO92/05828) comprises a 18 cannula which may be inserted into the body through a narrow opening. The cannula houses a piston which is 19 20 slidable within the cannula and manipulates a needle. 21 The needle is retained inside the cannula during insertion of the cannula into the patient. 22 The needle is formed from elastic material and when retained 23 inside the cannula, the needle is held in a generally 24

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1 straightened configuration. When the cannula is in 2 place, the needle can then be projected from the end of 3 the cannula to penetrate tissues and join wounds. 4 Other items such as ring clips can be manipulated using 5 the device. Several needles can be stored in the 6 device in a straightened configuration. In such a 7 configuration the needles exert a force on the device 8 in an attempt to reform to their unstressed 9 configuration. This causes difficulty in moving the needles within the device. 10 11 According to the present invention there is provided a 12 13 device for the delivery of a shape memory securing member into a confined space, the device having an exit 14 for the securing member and means to move the securing 15 16 member through the exit, the device further including a 17 magazine having a plurality of channels each of which 18 can store a securing member. 19 Preferably, each securing member is restrained in the 20 21 device in a first configuration, and upon passing 22 through the exit adopts a second configuration. Also preferably, each channel is separately alignable 23 24 with the exit. 25 26 One preferred form of magazine is a barrel. The barrel 27 may be rotatable around an axis and the channels may be 28 disposed parallel to said axis or may lie in a helical 29 configuration. This arrangement can be likened to a "revolver barrel" on a firearm. 30 31 32 The first configuration in which the securing members 33 are held inside the device is optionally straight. 34 However, the securing members may be held in the device in a generally helical configuration. This partially

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relaxes the securing members and allows the use of high 1 curvature securing members which cannot easily adopt a 2 3 straightened configuration. The high curvature securing members can form tighter coils when they pass 4 5 through the exit of the device. Preferably, the second configuration is the form of a 7 coil or loop. The coils may be overlapping (like a key 8 ring) or may be partially open. The second 9 10 configuration is preferentially adopted by the securing 11 member in the absence of any other force. The loops of 12 the second configuration may be round or some other 13 shape such as a rounded oblong or a round cornered triangle. On leaving the device the securing member 14 15 automatically adopts the second configuration, which is 16 the preferred shape according to the shape memory of 17 the member. 18 19 The channels may include or be in the form of tubes which may themselves move within the device. 20 21 The securing members may be housed within the tubes. The means to move the securing members may act upon the 22 securing members direct or upon the tubes, to move a 23 24 tube and a securing member housed therein towards the 25 exit. 26 27 When the securing members are stored within tubes, the tubes can be manipulated within the device more easily 28 than the securing members alone. The tubes may be 29 30 stored in parallel in the barrel, or may be stored sequentially in a line. The exit of the device may be 31 so arranged as to contain the tubes but allow the 32 33 securing members to pass from the tubes through the exit. 34 35

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1 The magazine may have indexing means to align a securing member with the exit or with a second channel 2 communicating with the exit. The indexing means may 3 also align the securing member with the means for 4 5 moving the securing member. 6 The magazine may also comprise other means of storing 7 8 the securing members, such that the securing members are sequentially arranged in a column, line, row or 9 helix, and are sequentially moved to the exit. 10 11 12 The magazine may be a replaceable element and may 13 contain only sutures or ligatures or a selection of 14 both, optionally in a defined order. The magazine(s) 15 may be colour-coded for ease of use. 16 17 The means for moving the securing members may be 18 disposed between the exit and the securing members, 19 such that the securing members are pulled towards the 20 exit, or alternatively, the securing members may be disposed between the exit and the means for moving the 21 securing members, such that they are pushed towards the 22 23 In the first arrangement, the means for moving the securing members may comprise an inch worm motor or 24 25 pinch wheel. 26 27 The exit of the device preferably comprises a tube which is curved in more than one plane. Optionally, 28 the tube is curved once or twice to lie in two or three 29 planes respectively and the exit is located at the end 30 of the tube. The tube may be of circular cross-section 31 32 or may be of a different cross-section, such as 33 rectangular or oval. 34 The exit tube may be sharpened so that it can penetrate 35

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tissue before the movement of the securing members 1 through the exit. This may be desirable where the 2 securing members do not easily penetrate the tissue surface. Where tissue penetration by an exit tube is 5 undesirable, the exit tube may be replaced by a tube 6 with a wide or bulbous end. The tube may be part of a 7 detachable assembly that allows re-orientation or extension of the assembly. The assembly can be 8 9 interchangeable with other forms of assembly to allow 10 the use of eg left and right hand forms and straight forms. 11 12 In an alternative form of the instrument, the exit may 13 14 be embedded in in a more substantial member such as a 15 half-round continuation of the main intrument body. One or more clamping jaws acting in opposition to the 16 exit (or its more substantial containment structure) 17 18 may be incorporated in order that it can easily be 19 penetrated by the sutures. The device than has dual 20 suturing and grasping functions. There may be two 21 moving jaws, one behind the other, so that two 22 connective folds of tissue may be grasped for suturing together. Each jaw would have a cutaway to allow 23 passage of the suture. The jaw(s) may be activated 24 25 from the handle by concentric connections on the instrument axis or in the form of external tubes. 26 27 28 In another embodiment of the invention, an ultrasonic 29 transducer may be incorporated in or near the exit. 30 This may be used to excite vibrations in the suture in 31 order to make it penetrate tissue more readily. 32 33 In some embodiments, joints between (for example) exit 34 tubes and other tubes in the device may be in the form 35 of collars, where one tube end fits within an end of

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1 another tube. This allows the securing members to be 2 moved past joints between tubes more easily. Preferably, the inner faces of all tubes used are 3 4 smooth. 5 The securing members are preferably formed from shape 6 7 memory alloy such as nickel-titanium (NiTi) alloy and 8 may comprise elongate strips of said alloy which are 9 coiled in the absence of any deforming force. securing members could also be formed from stainless 10 11 steel, from another biocompatable material (or coated 12 material) or from material which is resorbable by the body. 13 14 The securing members may be in the form of sutures 15 which have at least one sharp end or may be in the form 16 of ligatures having blunt ends. In the case of the 17 ligature, the surgeon holds the exit of the device next 18 19 to the body part to be ligated (eg, a blood vessel) and the ligature will wrap itself around the body part as 20 21 it is expelled. Securing members in the form of 22 sutures are formed with a sharp point at the leading 23 The surgeon then places the device so that the 24 point of the exiting sutures penetrates the tissue(s) 25 to be sutured. The suture then re-coils upon exit and creates a join in the tissue(s). Also in the case of a 26 suture, the exit tube may be required to deliver the 27 28 suture in a plane normal to the axis of the instrument. 29 30 A further advantage of the delivery device according to 31 one embodiment of the present invention is that it can store several sutures or ligatures to allow multiple 32 placements without the need to withdraw the instrument 33 34 from the patient.

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1 According to a second aspect of the present invention 2 there is provided a device for the delivery of a shape memory securing member into a confined space, the 3 device having an exit for the securing member, means to 4 move the securing member through the exit, and means 5 6 for cutting the securing member, preferably once a 7 portion thereof has been passed through the exit. 8 9 Preferably, upon leaving the device, the expelled 10 portion of the securing member automatically adopts a 11 configuration in accordance with its shape memory. 12 The device according to the second aspect of the 13 14 invention preferably contains a securing member in a continuous form, such as a roll, helix or coil. 15 configuration of the securing member preferably changes 16 as it passes between the interior and exterior of the 17 device. Thus when the securing member is in the form 18 19 of a high-curvature coil of shape memory alloy, it can 20 be maintained in a relaxed state (at or near its 21 preferred shape according to its memory) when stored 22 within the device, and need only be subjected to stress when its configuration changes upon leaving the device. 23 24 25 The means for cutting the securing member is preferably 26 disposed adjacent the exit so as to cut the securing 27 member as it leaves the device. The means for cutting 28 and the means for expelling may be provided by a single 29 element, for example, a pinch wheel. The means for 30 cutting may include means for sharpening the end of the 31 securing member left inside the device. 32 33 The present invention further provides a shape memory 34 securing member for use in a device as defined above, 35 the securing member having the form of a loop, coil or

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a helix in the absence of any force acting upon it. 1 2 3 Embodiments of the present invention will now be described by way of example only and with reference to 4 the accompanying drawings in which: 5 6 Fig. 1a shows a top view of a delivery device; 7 8 Fig. 1b shows a side view of the device of Fig. 9 1a; Fig. 1c shows an end view on A of Fig. 1a. 10 Fig. 2a shows an end view of a barrel of the 11 12 device of Fig. 1; Fig. 2b shows a longitudinal sectional view along 13 line B-B through the barrel of Fig. 2a; 14 15 Fig. 2c shows the opposite end view of the barrel of Fig. 2a; 16 Fig. 3 shows a detailed sectional view of the end 17 18 of the device of Fig. 1 with the barrel of Fig. 2a 19 in place; 20 Fig. 4a. shows a side view of the device of Fig. 1 21 with the barrel of Fig. 2a removed; and Figs 4b and 4c show one end of second and third 22 23 devices with an embedded exit and with a jaw for holding tissue against the exit. 24 25 Referring to Fig. 1a, b and c, a delivery device 1 has 26 27 a housing 5 in the form of an elongate tube of an exemplary diameter of 10mm which has at one end a 28 pistol grip 10 and at the other end a cut away section 29 30 The cut-away section 6 is adapted to accept a magazine in the form of a barrel 15 which generally 31 32 conforms to the outer shape of the housing 5 so as to 33 fit into the cut-away section 6.

35 The housing 5 has a exit tube 20 attached to one end

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thereof and communicating with the interior of the 1 2 housing 5. The exit tube 20 curves twice and has an exit 21 which faces one side of the device 1. The embodiment shown 5. is one adapted for delivery of sutures and delivers the 6 suture in a plane normal to the axis of the device. 7 The device of the invention may also be used for 8 delivering ligatures and in such a case, the exit tube 9 preferably curves once only and the second curve shown 10 11 in the exit tube 20 is not required. 12 Referring now to Fig. 2a, b and c, the barrel 15 13 comprises an inner hollow cylinder 15a and an outer 14 hollow cylinder 15b. The outer cylinder 15b has twelve 15 grooves 25 on the inner surface thereof which extend 16 along the length of the cylinder 15b. The grooves 25 17 are preferably formed by wire erosion and in the 18 example shown have a diameter of 0.3mm. 19 cylinders 15a and 15b can be fitted together as shown 20 in the drawings such that the grooves 25 form channels 21 from one end of the barrel 15 to the other. Securing 22 members are disposed in the grooves 25 in use of the 23 24 The securing members are typically formed from shape memory alloy wire such as NiTi wire and in the 25 26 present example, are 0.25mm in diameter. The inner cylinder 15a has an axial bore 28 extending 27 therethrough and in one end face 12 has indentations 30 28 29 which extend a short distance into the cylinder 15a in an axial direction. In the opposite end face of the 30 31 inner cylinder 15a is a slot 32 which intersects with the end of the bore 28. 32 33 Referring now to Fig. 3, the end of the device 1 which 34 holds the barrel 15 has an end stop 35 located after 35

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the cut-away section 6. The end stop has an axial 1 2 indentation or bore 29 on the internal face extending at least partially along the axis of the end stop 35 3 and which is co-axial with bore 28 when the barrel 15 4 5 is in place in the cut-away section 6. The end stop 35 6 also has an annular arrangement of twelve bores 38 in 7 its inner face in which are located springs 40 and ball bearings 42. The springs 40 bear on portions 35a of 8 9 the outer wall of end stop 35 and exert force on the 10 ball bearing 42 so as to expel them from the bores 38 in the direction of the pistol grip 10. Typically, the 11 12 ball bearings 42 are restrained from leaving the bores 38 entirely and may be held captive on the springs 38 13 or embedded in the end stop 35. 14 15 16 When the barrel 15 is in place in the cut-away section 17 6, the ball bearings 42 are forced out of the bores 38 and engage with the indentations 30 in the barrel 15. 18 19 Thus a series of twelve detent positions is 20 established. 21 22 An axle 50 (shown in Fig. 4a) is withdrawn from the 23 cut-away section 6 by a handle 51. The barrel 15 (not 24 shown in Fig 4a) is loaded with twelve securing members 25 such as sutures formed from NiTi shape memory alloy, and is located in the cut-away section 6. 26 27 are held in a generally straightened configuration in the grooves 25 of the barrel 15. The axle 50 is then 28 29 moved towards the end stop 35 by manipulating the 30 handle 51 such that the axle 50 passes through the bore 31 28 and engages in the axial bore 29 in the end stop 35. 32 Additionally a pair of projections 52 on the axle 50 33 are disposed in the slot 32 on the barrel 15 thereby 34 locking the barrel 15 against axial rotation with 35 respect to the axle 50. The barrel 15 is thereby

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locked in place in the cut-away section 6 and can be 1 rotated through its detent positions by manipulation of 2 the axle 50. The detent positions are held by the 3 action of the ball bearings 42 engaging in the 4 indentations 30. 5 6 The barrel 15 is released by sliding back the handle 51 7 so as to disengage the projections 52 from the slots 32 8 and the axle 50 from the bore 28. The barrel 15 can 9 then be removed and reloaded or replaced with one 10 already loaded. 11 12 In each of the detent positions a respective one of the 13 grooves 25 is in line with the exit tube 20, thus 14 allowing a securing member (not shown) such as a suture 15 or ligature to be expelled from the groove 25 through 16 the exit tube 20 and out of the exit 21. 17 18 The housing 5 also includes a flexible push wire 55 19 which is supported in a guide tube 58. The end of the 20 guide tube 58 is in line with the exit tube 20 and with 21 a respective one of the grooves 25 when the barrel 15 22 is in a detent position. 23 24 The push wire 55 is slidable in the guide tube and can 25 be moved so as to protrude into a respective one of the 26 grooves 25 when the barrel 15 is in a detent position 27 in the cut-away section 6. The push wire 55 is clamped 28 by a sliding clamp 60 which is moved by a rack and 29 pinion mechanism 65 located in the pistol grip 10. 30 rack and pinion mechanism 65 is in turn activated by a 31 trigger 70. 32 33 The rack and pinion mechanism 65 has gears which 34 increase the movement of the trigger 70 and reverse its

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direction so as to advance the clamp 60 towards the 1 2 barrel 15 located in the cut-away section 6. 3 Movement of the push wire 55 along the support tube 58 4 5 and into the groove 25 expels a securing member located 6 therein from the exit tube 20. Thus actuation of the 7 trigger 70 causes the push wire 55 to push a securing 8 member from one of the grooves 25 out of the exit tube 9 20. Upon leaving the exit tube 20, the securing member 10 no longer has any force acting upon it to maintain it in its straightened configuration, and it re-coils into 11 12 its preferred shape memory configuration of a loop or 13 coil. 14 15 The movement of the trigger 70 could also cause the barrel 5 to rotate through one detent position so that 16 the next groove 25 is aligned with the exit tube 20 and 17 the support tube 58. The barrel-rotation mechanism 18 19 (not shown) is similar to the mechanisms found in some 20 ball-point pens. 21 22 Different barrels may hold different securing members 23 for different purposes, or a single barrel may hold a number of different securing members. 24 25 26 Figure 4b shows the end of a second device according to 27 the present invention, having its exit 72 embedded in a 28 semi-circular extension 74 of the main body of the 29 device 76. Adjacent the exit 72 is a moveable clamping 30 jaw 78, in which is a cutaway 80 through which an 31 exiting securing member can pass. Tissue can be 32 grasped between the exit 72 and the jaw 78. Figure 4c shows a third device having two moveable jaws 82 33 34 opposite the device exit 84.

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1 Modifications and improvements may be incorporated

without departing from the scope of the invention.

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2 3

A device for the delivery of a shape memory 1. 4 securing member into a confined space, the device 5 having an exit for the securing member and means 6 to move the securing member through the exit, the 7 device further including a magazine having a 8 plurality of channels each of which can store a 9 securing member. 10

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A device as claimed in Claim 1 wherein each 2. 12 channel of the magazine is separately alignable 13 with the exit. 14

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A device as claimed in Claim 1 or Claim 2 wherein 3. 16 the or each securing member is restrained in the 17 device in a first configuration, and upon passing 18 through the exit adopts a second configuration. 19

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A device as claimed in any one of Claims 1 to 3 21 4. wherein the or each securing member is made from 22 nickel-titanium alloy or stainless steel. 23

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A device as claimed in any one of the preceding 25 5. Claims wherein the magazine is a barrel. 26

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6. A device as claimed in Claim 5 wherein the barrel 28 is rotatable about an axis. 29

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A device as claimed in Claim 6 wherein the 7. 31 channels are arranged along the barrel and 32 33 disposed parallel with the axis.

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A device as claimed in Claim 6 wherein the 35 8. channels are arranged along the barrel and 36

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disposed in a helical configuration to the axis. 1 2 A device as claimed in any one of Claims 3 to 8 9. 3 wherein the second configuration is the form of a coil or loop. 5 6 10. A device as claimed in any one of Claims 3 to 9 7 wherein the second configuration of the securing 8 member is the preferred shape according to the 9 shape memory of the securing member. 10 11 A device as claimed in any one of the preceding 12 Claims wherein the magazine is lockable within the 13 device. 14 15 A device as claimed in any one of the preceding 12. 16 Claims wherein the magazine is loaded with a 17 plurality of securing members. 18 19 A device as claimed in any one of the preceding 20 13. Claims wherein the channels include or be in the 21 form of tubes. 22 23 A device as claimed in any one of the preceding 24 14. Claims wherein the magazine has indexing means to 25 align a securing member with the exit or with a 26 second channel communicating with the exit. 27 28 A device as claimed in Claim 14 wherein the 29 15. indexing means aligns the securing member with the 30 means for moving the securing member. 31 32 A device as claimed in any one of the preceding 33 16. Claims wherein the magazine is removable from the 34 device. 35

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		16
1	17.	A device as claimed in any one of the preceding
2		Claims wherein the means for moving a securing
3		member is disposed between the exit and the or
4		each securing member.
5		
6	18.	A device as claimed in any one of Claims 1 to 16
7		wherein the or each securing member is disposed
8		between the exit and the means for moving the
9		securing member.
10		
11	19.	A device as claimed in Claim 18 wherein the means
12		for moving the securing member is a push wire.
13		
14	20.	A device as claimed in Claim 19 wherein the push
15		wire is flexible and slidable in a guide tube.
16		
17	21.	A device as claimed in any one of the preceding
18		Claims in which the exit comprises a tube.
19		
20	22.	A device as claimed in Claim 21 wherein the free
21		end of the tube is sharpened.
22		
23	23.	A device as claimed in Claim 21 or Claim 22
24		wherein the tube is curved.
25		
26	24.	A device as claimed in any one of Claims 21 to 23
27		wherein the tube is detachable.
28		
29	25.	A device as claimed in any one of the preceding
30		Claims wherein the device includes one or more
31		clamping jaws acting in opposition to the exit.
32		
33	26.	A device as claimed in Claim 25 wherein one or
34		more of the jaws is moveable, and wherein a
35		securing member is passable through one or more of
36		the jaws.

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17 27. A device as claimed in any one of the preceding 1 Claims wherein the device includes an ultrasonic 2 transducer located in or near the exit. 3 4 28. A device for the delivery of a shape memory 5 securing member into a confined space, the device 6 having an exit for the securing member, means to 7 move the securing member through the exit, and 8 means for cutting the securing member or a portion 9 of the securing member that has passed through the 10 exit. 11 12 29. A device as claimed in Claim 28 wherein the 13 expelled portion of the securing member 14 automatically adopts a configuration in accordance 15 16 with its shape memory. 17 30. A device as claimed in Claim 29 wherein the 18 adopted configuration is a coil or loop. 19 20 31. A device as claimed in Claim 28, 29 or Claim 30 21 wherein the securing member in the device is in a 22 23 continuous form. 24 25 A device as claimed in Claim 31 wherein the 26 configuration of the securing member changes as it passes between the interior and exterior of the 27 device. 28 29 A device as claimed in any one of the Claims 28 to 30 33. 32 wherein the means for cutting the securing 31 32 member is disposed adjacent to the exit. 33 A device for the delivery of a shape memory 34 34. securing member into a confined space, the device 35

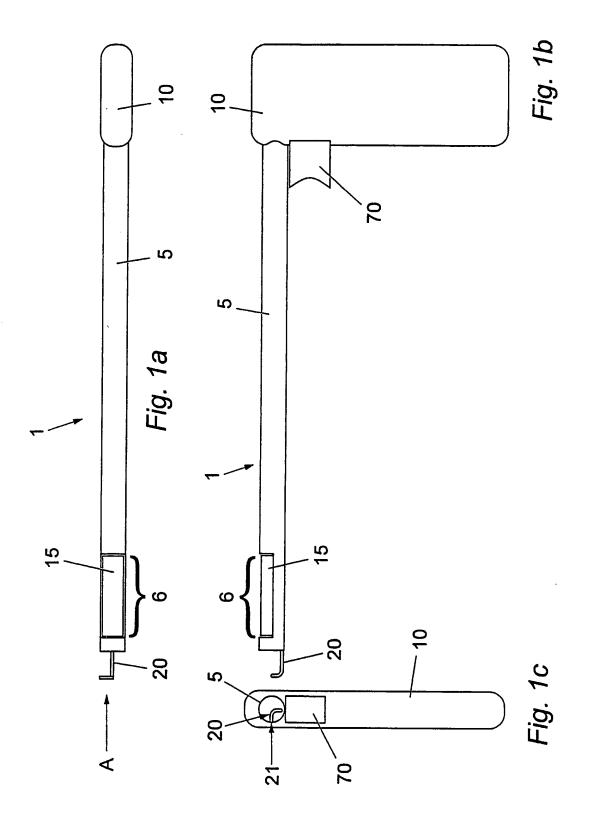
having an exit for the securing member and means

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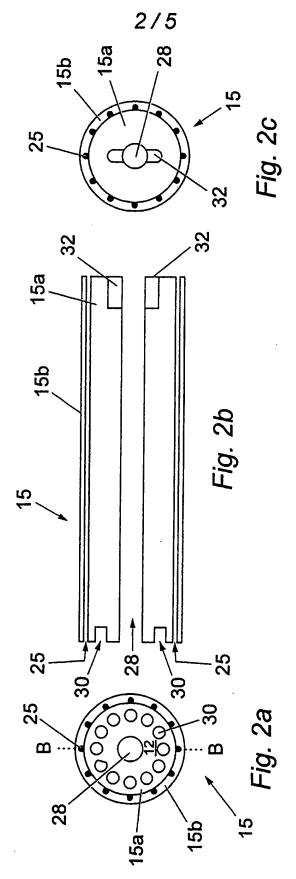
		10
1		to move the securing member through the exit,
2		wherein the securing member is stored in the
3		device in an arcuate configuration.
4		
5	35.	A device as claimed in Claim 34 wherein the
6		securing member is stored in the device in a
7		helical configuration.
8		
9	36.	A device as claimed in any one of preceding Claims
10		for use as a surgical instrument.
11		
12	37.	A device as claimed in Claim 36 wherein the
13		securing member is a suture or a ligature.
14		
15	38.	A device as claimed in any one of the preceding
16		Claims wherein the device includes a handle and
17		includes a trigger means to operate the means to
18		move the securing member.
19		
20	39.	A shape memory securing member for use in a device
21		as claimed in Claims 1 to 38.
22		
23	40.	A method of delivering a securing member into a
24		confined space using a device as defined in Claims
25		1 to 38 wherein at least the exit of the device is
26		located within the confined space, and the means
27		to move the securing member is activated to
28		deliver the securing member from the device
29		through the exit.
30		
31	41.	A method as claimed in Claim 40 wherein the
32		securing member changes from a first configuration
33		in the device to a second configuration upon
34		passing through the exit.
35		

36 42. A device for the delivery of a sharp memory

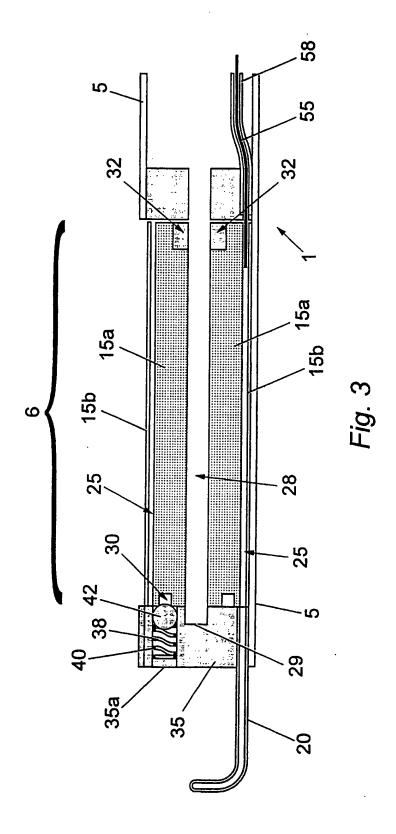
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2	substantially as herein defined and with reference
3	to Figs 1a, b, c, 2a, b, c, 3 and 4a.
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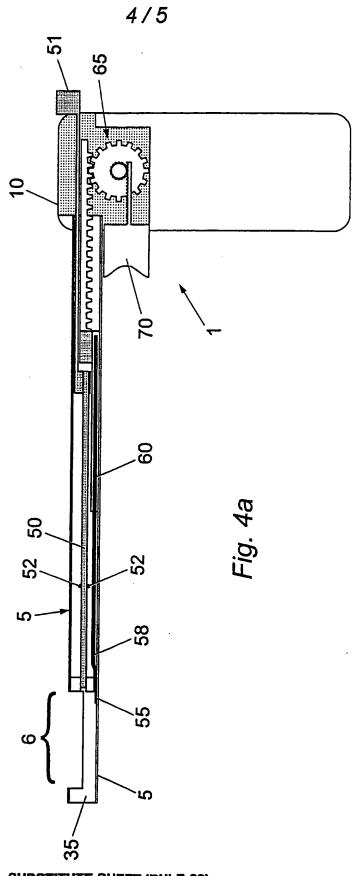
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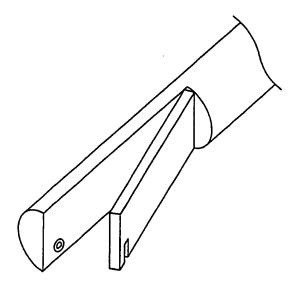


Fig. 4b

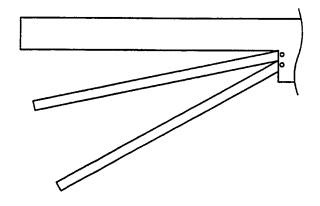


Fig. 4C SUBSTITUTE SHEET (RULE 26)

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